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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,916	10/02/2000	Carl Anthony Blau	UOFW115624	4343

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EXAMINER
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ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 11/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/582,916	Applicant(s) Blau et al.
	Examiner Anne Marie Wehbé	Art Unit 1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 30, 2002* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-88* is/are pending in the application.

4a) Of the above, claim(s) *43, 54, 67-69, and 77-88* is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-42, 44-53, 55-66, and 70-76* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Applicant's response to the restriction requirement received 8/30/02 has been entered. Applicant's election of Group I, and the species of hematopoietic stem cells is acknowledged. Claims 1-88 are pending in the instant application. Of these, claims 43, 54, 67-69, and 77-88 are withdrawn from prosecution as being drawn to subject matter non-elected without traverse in paper no. 12. Claims 1-42, 44-53, 55-66, and 70-76 are currently under examination. An action on the merits follows.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35

U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-42, 44-53, 55-66, and 70-76 are rejected under 35 U.S.C. 102(e) as being anticipated over U.S. Patent No. 5,741,899 (4/21/98), hereafter referred to as Capon et al. The applicant claims a method for rendering a subpopulation of primary cells susceptible to drug-induced growth comprising transducing the cells with a recombinant DNA encoding a fusion protein comprising at least one signaling domain and at least one heterologous drug-binding domain. The applicant further claims said method wherein the cells are exposed to the drug. The applicant's claims are also drawn to cells transduced with said recombinant DNA., particularly hematopoietic stem cells.

Capon et al. teaches the transduction of cells with either 1) a chimeric protein comprising an extracellular inducer-responsive clustering domain capable of binding an extracellular inducer that transmits a signal to a proliferation signaling domain, a transmembrane domain, and a proliferation domain that signals a host cell to divide, or 2) a chimeric protein comprising an intracellular inducer-responsive clustering domain capable of binding an intracellular that transmits a signal to a proliferation signaling domain and a proliferation domain that signals a host cell to divide (abstract, and columns 1-2). In particular, Capon et al. teaches that the extracellular or intracellular inducer-responsive clustering domain of the chimeric protein is derived from immunophilin, e.g. FKBP, and that the cytoplasmic signal transduction domain is derived from

homodimerizing receptors such as G-CSFR, EPO-R, GHR, PRLR, TPOR, and gp130 (Capon et al., columns 7, 9, 13, 15, 34-35, and 42-43). Capon et al. further teaches that cells transduced with an appropriate vector, such as a viral vector or DNA plasmid, encoding said chimeric protein can be induced to expand and proliferate by exposing the cells to a multivalent inducer molecule capable. In the case of chimeric proteins which encode FKBP, Capon et al. teaches that the inducer molecule is a multivalent cell-permeant drug with a molecule weight of less than 5 kD such as FK1012 (Capon et al., columns 15, 19, 21 and 22). In addition, Capon et al. teaches that target cells for expansion can be transduced in vitro or in vivo for use in the treatment of human diseases such as cancer or autoimmune disease (Capon et al., columns 1, 16 and 21-22). In regards to cells transduced ex vivo and introduced into the host mammal, Capon et al. teaches that the cells can be allogeneic or autologous cells, including hematopoietic stem cells capable of developing into cells of the myeloid and lymphoid lineages (Capon et al., columns 16, and 21-22). Thus, by teaching all the elements of the claims as written, Capon et al. anticipates the instant invention as claimed.

In regards to the particular use of the method taught by Capon et al. to treat hematopoietic disease or pathological conditions in a mammal or to obtain megakaryocytes, neutrophils, or erythrocytes in vivo or in vitro, please note that the methods for inducing the proliferation of hematopoietic stem cells taught by Capon et al. include the exact same method steps as those recited in claims 56-66 and 70-76. It is a general rule that merely discovering and claiming a new benefit to an old process cannot render the process again patentable. In re

Woodruff, 919 F. 2d 1575, 1577-78, 16 USPQ2d 1934, 1936-37 (Fed.Cir. 1990); In re Swinehart, 439 F.2d 210, 213, 169 USPQ 226, 229 (CCPA 1971); and Ex Parte Novitski, 26 USPQ2d 1389, 1391 (Bd. Pat. App. & Int. 1993). Furthermore, as noted above, Capon et al. does specifically teach the use of the disclosed methods for treating disease, and clearly teaches that hematopoietic stem cells develop into myeloid and lymphoid cells (Capon et al., columns 16 and 21-22). The MPEP also states that "when the claim recites using an old composition or structure and the 'use' is directed to a result or property of that composition or structure, then the claim is anticipated. *In re May*, 574 F. 2d 1082, 1090, 197 USPQ 601, 607 (CCPA 1978)" MPEP 2112.02. Thus, by teaching the exact same compositions and method steps recited in the instant claims, Capon et al. anticipates the instant invention as claimed.

Information Disclosure Statement

The supplemental information disclosure statement filed 8/30/02, paper no. 11, fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because it has not been signed by the attorney of record. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining

compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 C(1).

No claims are allowed.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (703) 306-9156. The examiner can be reached Mon-Thurs and every other Friday from 9:30-7:00. If the examiner is not available, the examiner's supervisor, Deborah Reynolds, can be reached at (703) 305-4051. General inquiries should be directed to the group receptionist whose phone number is (703) 308-0196. The technology center fax number is (703) 308-4242, the examiner's direct fax number is (703) 746-7024.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER